JUL 25 2012

SECTION 5: 510(K) SUMMARY

Device:	**AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber**
Applicant:	ConvaTec Inc.
Contact:	Katrina Fiedler Associate Director, US Regulatory Affairs 908-904-2541 Fax: 908-904-2235 Email: katrina.fiedler@convatec.com
Date:	April 25, 2012
Trade Name:	AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber
Classification Name:	Dressing, Wound, Drug
Device Class:	Unclassified
Product Code:	FRO

Predicate Device: AQUACEL™ Ag Hydrofiber™ Dressing, K080383

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a one piece wound dressing comprised of two layers of soft, sterile non-woven material. The non-woven pads are comprised of Hydrofiber™ dressing and ionic silver stitchbonded together with regenerated cellulose fibers and designed to provide additional absorbency and tensile strength properties. This conformable and highly absorbent dressing absorbs wound fluids, creating a soft gel which maintains a moist environment and supports the body's healing process.

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; partial thickness (second degree) burns; diabetic foot ulcers, (venous stasis

ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); surgical wounds left to heal by secondary intention such as dehisced surgical incisions; surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular); traumatic wounds; wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites; oncology wounds with exudate, such as fungoids-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; painful wounds and infected wounds.

Since AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is largely based on the AQUACEL™ Ag Hydrofiber™ technology, the safety and effectiveness of AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber has been demonstrated by the literature and clinical data provided in previous 510(k)s (i.e., K080383). In summary, a careful and thorough review of the literature suggests that Hydrofiber™ dressings have been used safely and effectively in clinical trials for the management of wounds.

Thus we believe that, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is substantially equivalent to the previously cleared Hydrofiber™-technology based products (reference K080383) and that AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber can be used safely and effectively for the management of wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Convatec, Incorporated
% Ms. Katrina Fiedler
Associate Director, US Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K121275
Trade/Device Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 25, 2012
Received: April 27, 2012

Dear Ms. Fiedler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

Device Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber

For Over-the-Counter Use:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds;
- Infected wounds

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120275